

RESPeRATE PATIENT ENROLLMENT AND ADMINISTRATION GUIDELINES

Indications:

The RESPeRATE is intended for use as a relaxation treatment for the reduction of stress by leading the user through interactively guided and monitored breathing exercises. The device is indicated for use only as an adjunctive treatment for high blood pressure, together with other pharmacological and/or non-pharmacological interventions.

Patient Enrollment Guidelines:

Ten clinical studies and physicians' experience with RESPeRATE show that the device is particularly helpful in the following clinical situations:

- White-coat or labile hypertensive patients who might benefit from reducing stress and sympathetic activity.
- Diabetic hypertensive patients.
- Patients with isolated systolic hypertension.
- Resistant hypertensive patients (uncontrolled BP despite the use of a diuretic and at least 2 other medications at maximum dosage).

Administration Guidelines:

Patients should be instructed to use the RESPeRATE device routinely at rest, in 15-minute daily sessions, aiming to accumulate at least 40 minutes of slow breathing per week (10 breaths per minute or less). The accumulated Weekly Therapeutic Time (minutes of slow breathing) appears on the device's display momentarily each time the device is turned on. Patients should be made aware that results, just like physical conditioning, may take a few weeks to become fully manifested and that without continued device use, any achieved benefits would likely be diminished. Studies show that a clinically significant, sustained reduction in BP occurs within 3 to 4 weeks of routine use.

For additional information please call toll free 1-800-509-2403